

### REMARKS

In the present amendment, claim 1 has been amended to clarify the claimed subject matter. In addition, claim 9 has been canceled. After entry of the present amendments, claims 1-7 will be pending.

#### **35 U.S.C. § 112, first paragraph**

Claims 1-7 and 9 stand rejected as purportedly not being enabled by the specification. That rejection is respectfully traversed to the extent the rejection applies to the claims as amended herein.

Applicants note that claim 1, as amended herein, is directed to a method for inhibiting the growth of hormone-dependent tumor cells. The claimed method comprises the element of administering to the patient a selective androgen receptor modulator (SARM) that has two particular features, i.e., that the SARM: exhibits antagonist activity inhibiting growth of said hormone-dependent tumor; and exhibits no activity or agonist activity against other, nontumor tissues containing the androgen receptor.

It is respectfully submitted that the subject matter of claim 1 is enabled by the specification. The Examiner's attention is directed to the sixty-seven particular compounds provided in the specification beginning at page 34, and the particular teachings in the specification including pages 44-46 demonstrating the enablement of the subject matter of claim 1. These teachings enable one of skill in the art to administer to a patient a selective androgen receptor modulator that exhibits antagonist activity inhibiting growth of said hormone-dependent tumor; and exhibits no activity or agonist activity against other, nontumor tissues containing the androgen receptor. Accordingly, withdrawal of this rejection is respectfully requested.

#### **35 U.S.C. § 103**

Claims 1-7 and 9 stand rejected as purportedly being unpatentable over Thorpe et al., in view of Zhi et al. and Li et al. That rejection is respectfully traversed to the extent the rejection applies to the claims, as amended.

The Examiner's position appears to be succinctly stated in the Office Action at page 10, first complete paragraph. Specifically, it is alleged that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the administration of selective androgen receptor modulators (as stated by Zhi et al. and Li et al.) in the methods of inhibiting and treating prostate tumor cells (as stated by Thorpe et al.) with a reasonable expectation of success. The motivation to do so is given by Thorpe et al. who teach developing

successful antitumor agents via selective target agents (col. 1, lines 65-67), and the teaching of Zhi et al. and Li et al. relating to compounds that target androgen receptors.”

Applicants respectfully submit, even assuming the combination of these three references is proper, that the combination of Thorpe et al., Zhi et al., and Li et al. does not teach all of the elements of Applicants’ claimed invention.

As recited in amended claim 1, the present invention is directed to a method for inhibiting the growth of hormone-dependent tumor cells, wherein this method includes the feature of administering to a patient a selective androgen receptor modulator (SARM) that has two particular features: exhibits antagonist activity inhibiting growth of said hormone-dependent tumor; and exhibits no activity or agonist activity against other, nontumor tissues containing the androgen receptor.

By contrast, the combination of Thorpe et al., Zhi et al., and Li et al. does not provide this feature, i.e., a SARM that (i) exhibits antagonist activity inhibiting growth of said hormone-dependent tumor and (ii) exhibits no activity or agonist activity against other, nontumor tissues containing the androgen receptor. The combination of Thorpe et al., Zhi et al., and Li et al. certainly does not teach or suggest SARMS having these two features, nor the claimed method of Applicants’ present invention. Thus, it should be apparent that claim 1 is patentable over the combination of Thorpe et al., Zhi et al., and Li et al. Applicants are the first to provide the teaching of the subject matter of claim 1 (as well as claims 2-7 which ultimately depend from claim 1). Withdrawal of this rejection is respectfully requested.


**CONCLUSION**

In view of the foregoing amendments and remarks, allowance of the application is respectfully requested. The Examiner is invited to contact the undersigned if there are any questions concerning the prosecution of this application.

The Commissioner is authorized to charge Deposit Account 19-3880 (Bristol-Myers Squibb Company) for any requisite fees due or to credit any overpayment.

Respectfully submitted,

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Date: April 13, 2004